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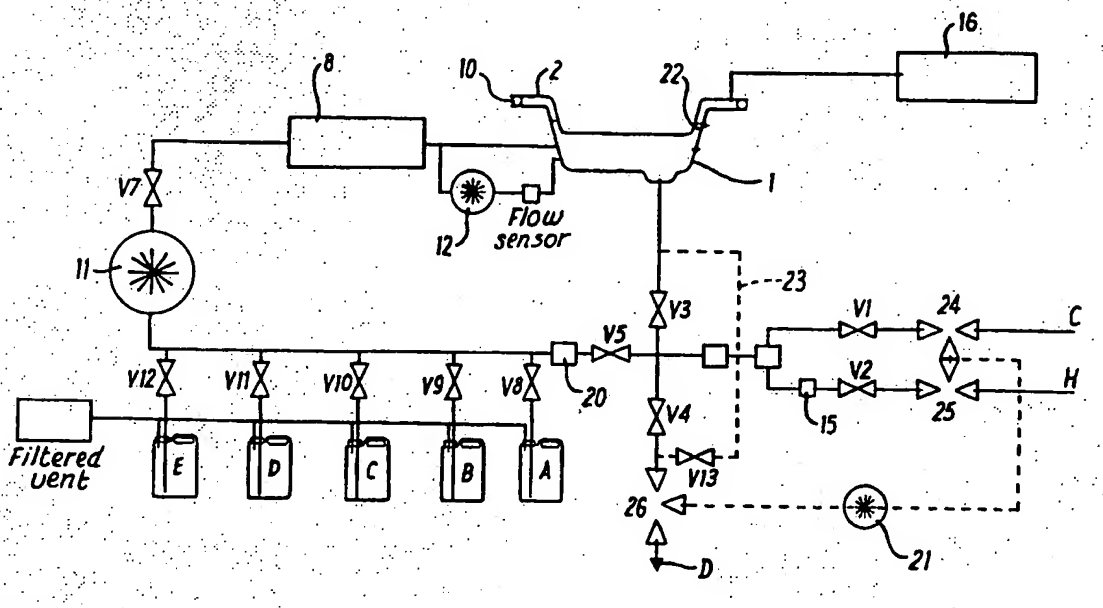

(57) Abstract

Apparatus for washing and disinfecting endoscopes comprises a housing (4) defining a chamber and a re-entrant lid (2) designed to be covered by disinfectant when the chamber is filled with disinfectant. Pipework connects disinfectant containers (A-E) to the chamber and an ultraviolet steriliser (8) is disposed in the pipework. Valves (V1-V14) are also disposed in the pipework to control the flow of liquid therethrough and sealable quick release connectors (24-26) connect the pipework to hot (H) and cold (C) water supplies and a drain (D). When released, the apparatus is sealed from external connectors. The apparatus enables the whole system including the chamber containing the endoscopes to be disinfected in an efficient and reliable manner.

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APPARATUS FOR AND METHOD OF DISINFECTION

The present invention relates to apparatus for and a method of disinfecting.

The invention is particularly, but not exclusively, intended for the disinfection of endoscopes. Disinfection in endoscopy is likely to assume increasing importance in view of the HIV epidemic and the increasing numbers of immune suppressed patients being investigated. Routine sterilization is not possible with endoscopes because of the delicate nature of the instrument, (i.e. lenses, controls etc.) At present endoscopes are sterilized using a combination of mechanical cleaning and soaking in the preferred disinfectant (2% Glutaraldehyde). Unfortunately this disinfectant is an irritant and is known to cause side effects in many staff. One solution is to use a sealed washing machine with an automatic cycle. A recent evaluation of four commercially available machines, however, has identified serious flaws in the wash cycle. In particular it was found that the machines could become colonised and transmit infection to the patient via the endoscope. The problem of colonisation arises from two problems. The first is that the lid of the enclosure containing the endoscopes is not adequately disinfected resulting in potentially contaminated water dripping onto the sterilised instrument after its

disinfection. Secondly, not all pipework is adequately disinfected leaving potential areas for bacterial colonisation. During rinse cycles these bacteria can infect the disinfected instrument. The current invention addresses these problems and also minimises the exposure of staff operating the machine to the disinfectant.

According to the invention there is provided apparatus for washing and disinfecting comprising a housing defining a chamber for accommodating items to be washed and disinfected characterised by a lid operative to close off the chamber and shaped so that when the chamber is filled with disinfectant the inside surface of the lid is completely covered by disinfectant, pipework operative to connect supplies of disinfectant to the chamber, a bacterial filter disposed in the pipework and valves disposed in the pipework and controlling the flow of disinfectant therethrough.

In order that the invention may be more clearly understood, one embodiment thereof will now be described, by way of example, with reference to the accompanying drawings, in which:-

Figure 1 diagrammatically shows apparatus for disinfection for use with endoscopes.

Figure 2A is a plan view of an immersion bath forming part of the apparatus of Figure 1,

Figure 2B is a partial cross-sectional view of the bath of Figure 2A, and

Figure 3 diagrammatically shows an alternative form of apparatus to that shown in Figure 1.

Figure 1 shows apparatus including schematic pipework with interconnecting valves V1 to V11 to achieve the required operation. An immersion bath 1 is schematically illustrated showing a re-entrant lid 2 which enables disinfection of all surfaces of the vicinity of the endoscopes 3 , which are laid into the body 4 of the bath 1 as shown in Figure 2. A seal 10 is disposed between the body 1 and the cover 2. A plurality of standard 5 litre disinfectant containers A to D respectively are connected through respective valves V8 to V11 and appropriate pipework and further valves to the system. Low and high liquid level sensors (not shown) are provided in respective containers. A liquid circulation pump 11 is provided. A high level float switch is also provided in the bath 1.

An input line 5 from a water mixer unit 6 passes via a filter 7 to remove debris and through an ultraviolet

filter 8 which kills any bacteria present in the water. The disinfectant is passed via valve, V3, through these filters ensuring their disinfection on every machine operation. In this way all parts of the machine and pipework within a washed "sterile" boundary are disinfected on every sterilisation cycle. This boundary is indicated by reference 9 in Figure 1.

The endoscope washing machine provides five main operations, these being:

a) Machine Disinfect
b) Endoscope Detergent Wash
c) Endoscope Disinfect
d) Endoscope Water Rinse
e) Endoscope Channel Drying

These operations essentially provide the building blocks for the main wash cycle which comprises operations b,c,d and e. Similarly, the auto disinfect cycle is formed from operations b,a and d.

The apparatus of Figure 1 incorporates the necessary features to achieve the above cycles.

The apparatus has the ability to disinfect incoming and recirculating water using the ultra violet water

purifier 8.

Another important advantage offered by the system is the machine disinfect cycle which would take place automatically prior to the start of a shift or work period. Also as a result of the chosen pipe work layout and machine operation, the machine and its flow circuit would effectively be disinfected during every endoscope washing cycle since common pipe work has been used for the supply and return of both water and disinfectant.

The machine uses the hospital's hot water supply, but as there is no guarantee that the hot water temperature will not exceed 50°C a means of limiting the water temperature is required. This is achieved by unit 6 which is identical to the type of valve presently used on hospital or hotel shower units. Although this valve can effectively maintain a water supply up to its set maximum temperature with only small variations in temperature, if no hot water is present then the unit continues to "mix" cold water. The hot and cold water supplies are referenced H and C respectively and are connected to the apparatus via respective non-return valves V12 and V13.

To prevent cold water from entering the immersion bath, a temperature sensor 15 is incorporated into the

machine's pipe work. This continuously monitors the temperature of water leaving the unit 6 such that if the water is below a minimum temperature a signal energises diverter valve V6 to direct cold water to drain. This signal could also be used to stop the machine after a preset time and/or alert staff who would either instruct the machine to continue using cold water or enable the operator to investigate why no hot water is available.

The layout of the pipe work and valves, is designed to be self draining, thereby avoiding potential water traps where bacteria could colonise.

The machine disinfect cycle is described below.

To disinfect the immersion bath 1, cover 2 and associated pipe work by circulating disinfectant around the system at the start of a shift, all surfaces must be wetted by disinfectant for a pre-defined length of time.

The cycle is started with valves V6 and V7 set as shown on Figure 1.

The liquid circulation pump 11 is started and valves V3, V4 and V8 opened to pump liquid into the immersion bath 1.

When the disinfectant level in container A falls sufficient so that the low level sensor in the container activates, valve V8 closes and valve V9 on container B opens to enable the filling of the bath to continue.

The fill cycle using container C and D (if required) is repeated until the bath is full; this will be sensed by a high level flow at switch in the immersion bath.

Valve V4 then closes and V5 opens to produce a flow of disinfectant around the circuit. Also a channel cleaning pump 12 starts to circulate disinfectant around the channel cleaning circuit 13 which comprises a filter 14.

Venting of air from the system during filling and emptying of the immersion bath is catered for using a filter 16 in the bath's cover 2. Similarly venting of the disinfectant containers will again be carried out via small individual filter units.

Disinfection of the machine will continue until a timer indicates the cycle has been completed, disinfectant will then be returned to storage containers as follows.

A control system is provided to interrogate each

container A to D to establish whether the containers are full, by using the high level sensors incorporated into each container.

The circulation pump 11 and channel pump 12 are stopped then valves V4, V8 to V11 and V12 are opened to return disinfectant to the storage containers. If any of the containers are full then their respective valves remain closed. Also when the disinfectant level in any container reaches the full level sensor, that containers valve closes to prevent overfilling.

The arrangement of the pipe work would be such that drainage of the system could be achieved without pools of fluid remaining in the pipe work. To ensure all disinfectant has been returned to the storage containers a float type sensor is included in pipe work slightly upstream of the containers, to warn the operator if all containers have been filled but disinfectant still needs to be drained.

If this case does arise then an empty container is incorporated into the system with suitable pipe work and valves, enabling the operator to operate a key switch or insert a PIN number to dump the excess disinfectant prior to changing the disinfectant containers and starting a further cycle.

With regard to machine disinfection, the machine's immersion bath and cover is fully disinfected during the machine disinfect cycle. This is achieved by forming the lid so that it sits inside the bath as shown. The lid incorporates the continuous peripheral seal 10 to prevent the escape of disinfectant vapour during operation.

Venting of the immersion bath enclosure is achieved by the filter unit 16 located in the baths cover. As this vent is situated above the liquid level it should not come into contact with water or disinfectant.

The size of the immersion bath is important since it determines the plan area of the machine. As the machine is required to be mobile, it must be capable of being wheeled through a standard 2'6" wide doorway. With this in mind the overall width of the machine has been set to 700mm or 2'3".

Having set the width of the machine to 700mm a number of alternative endoscope layouts were considered. In carrying out this exercise attention was directed to obtaining simply layouts into which staff could easily locate endoscopes of different designs in readiness for cleaning. The other factor influencing the layout of the immersion bath was the need to avoid subjecting the

endoscopes' cables to excessively sharp bend radii whilst taking account of the endoscope umbilical end attachments.

Since the size and layout of the immersion bath, to a large extent determines the volume of disinfectant required together with that for the water used during the detergent wash and rinse cycles, it is important to keep this volume to a minimum. In practical terms it is anticipated that approximately 20 litres of liquid will be required to fill the bath and associated pipe work.

The other cycles (a) to (d) referred to earlier are accomplished in a similar manner by the appropriate sequencing of the valve work.

The final cycle, to remove water from the internal channels of the endoscope by passing air through the passage ways is described as follows.

The cycle starts with all valves closed and valves V6 and V7 set as shown on Figure 1.

From the previous wash and disinfect cycles the endoscopes internal channels will already be connected to the channel pump cleaning circuit.

As the immersion bath and pipe work system will have been previously drained at the end of the water rinse cycle, the channel pump being diaghragm pump can be started to pump air from the immersion bath through the pump, then the endoscope, and back into the immersion bath.

Since the bath and endoscope have been rinsed earlier with water at 50°C it expected that of the heat from the water will have transferred to the endoscope and bath thereby eliminating the need to heat the air prior to circulating it through the endoscope.

The machine is designed to use standard containers of disinfectant such that on changing disinfectant there is minimal staff contact with the vapours given off. Standard containers supplied direct from the manufacturer are simply activated and connected into the system. Containers containing discarded fluid are removed and disposed off. This obviates the requirement to pour disinfectant from one container to another. In all other respects the system is sealed, air movements being through a charcoal or other similar filter, the job of which is to remove disinfectant vapour.

For the detergent cycle it is necessary to add either liquid or solid soap to the system. It is

proposed that this is inserted into a container located in the bath itself when the instruments are loaded. The device holding the soap to be fitted with a sensor to ensure that the cycle cannot proceed without detergent having been inserted. The use of reservoirs of liquid detergent is to be avoided as these have been found to become colonised by bacteria.

A second embodiment of the invention is described below with reference to Figure 3. In this figure corresponding parts bear the same reference numerals.

This embodiment differs from the first in two major respects. First, the valve circuit is arranged to facilitate a manifold mono-block construction for the majority of the valves in order to minimise the extent of the internal pipework. A low level sensor 20 shown in Figure 3 is located in this manifold. Secondly, the circuit shown in figure 3 includes a schematic representation of three quick-release couplings 24, 25 and 26 inserted into the two water supply H and C and the drain circuits D. These couplings are widely available with automatic closure valves which activate on release to provide a seal-on-break feature.

The object is to isolate the machine from the external water supplies and drain facilities by first

disconnecting the flexible external pipes from those facilities and reconnecting them to the corresponding port provided. In this state, the machine, all its pipework and its associated parts, including its external flexible pipes, comprise a sealed system. In the machine disinfection cycle, the disinfectant can then be circulated through every component giving complete disinfection of all internal surfaces. If the machine in this state is filled with, or exposed to disinfectant, by circulating flow for more than 12 hours continuously, the machine can be considered then to be sterile.

It is the intention that the machine disinfection cycle would be used at the end of a shift, usually overnight. The machine would be left in the sealed state, filled with disinfectant until the start of the next shift. In this way a new shift starts with a sterile machine.

Only one part of the machine is not in contact with liquid disinfectant and that is the seal 10 between the lid 2 and the bath 1. This seal is constructed from a seamless loop of appropriate material and is located in a suitable groove such that it can easily be removed for cleaning, disinfection and/or sterilisation as appropriate. This would be done as part of routine cleaning and maintenance. At this time, the seal location

and adjoining areas of the bath and lid can also be cleaned and disinfected. At appropriate times, a new sterile seal can be fitted. Seals and their associated housings, fulfilling the above requirements, can easily be designed by one skilled in the art.

The operation of the machine disinfection cycle is described below with reference to Figure 3. Before this cycle proceeds, the following start-conditions should be met:

U.V. Water Disinfector lamp off
Immersion Bath Lid Sensor - sensing
Water Temperature Sensor - not active
Manifold Low-Level Liquid Sensor - not active
Disinfectant Low-level Sensors - sensing
Disinfectant High-Level Sensors - not active
All solenoid valves de-energised (all valves are in the closed state when de-energised).
Circulation Pump stopped
Channel Pump stopped
Auxiliary Pump stopped

As described earlier, prior to the start of the machine disinfection cycle, the operative should connect the water inlet pipes and drain hoses to their respective reconnection ports mounted on the external surface of the

machine.

Initially, solenoid valves V8 through to V12 energise (open), flow reducing valve, V7, energises and the main circulation pump 11 starts.

After say 40 seconds, solenoid valves, V1 through to V4, energise, and the channel and auxiliary pumps 12 and 21 start.

Filling of the Immersion bath continues until the slow-fill level sensor, located in the bath, activates and instructs the controlling electronics to de-energise (close) the flow-reducing valve, V7.

The slow-fill state continues until a bath high-level sensor 22 activates, this de-energises solenoid valves, V8 through to V12, and energises solenoid valve, V5, to produce a recirculating flow circuit for disinfectant through the bath and associated components.

After say 30 seconds, solenoid valve, V13 is energised and valve V4 is de-energised, forcing disinfectant through a vent line 23. After say a further 30 seconds these two solenoid valves are then returned to their original states. The vent line and associated

valve, V13 has been included to prevent the auxiliary pump from being air-locked, as this pump is attached to the drain port which is the lowest point of the circuit. The auxiliary pump is required to return disinfectant to the containers from this lowest point of the circuit.

Whilst valves V13 and V4 are being cycled, valve, V1, de-energises for 15 seconds forcing all flow through valve, V2. Valve, V1, is then re-energised and valve, V2, de-energises for 15 seconds, this time forcing flow through valve V1; valve V2 is then re-energised.

Once the set machine disinfection time has expired, the circulation, channel and auxiliary pumps are stopped and solenoid valves, V6 through to V11, are energised, thus enabling the disinfectant to drain back to the storage containers.

When the level of liquid in the manifold has drained sufficiently so that the manifold Low-Level Liquid sensor is indicating that no liquid is present, solenoid valve, V4, is de-energised and valve, V12 energised. The auxiliary pump 21 is started to remove liquid from the drain hose. Similarly, the channel pump is started to clear any remaining liquid from this part of the circuit. Whilst the auxiliary pump 21 is running, valves, V1 and V2, should be alternately energised and de-energised to

clear any residue liquid from the water inlet pipes.

To clear any remaining liquid from the circulation pump 11 and ultra violet steriliser bacterial filter 8, the circulation pump is run backwards briefly for say 15 seconds. After say a further 20 seconds all pumps should be stopped and all valves de-energised.

The machine now waits for the operator to acknowledge that reconnection of the water supply and drain hoses has been completed before continuing with a water rinse cycle to purge any residual disinfection vapour from the machine's bath and pipework.

The machine is now in a disinfected state waiting for normal operation to commence. This comprises the normal wash; disinfect, rinse and channel drying sequences of medical instruments as described in the first embodiment.

It will be appreciated that the above embodiment has been described by way of example only and that many variations are possible without departing from the scope of the invention.

CLAIMS

1. Apparatus for washing and disinfecting comprising a housing (4) defining a chamber for accommodating items to be washed and disinfected characterised by a lid (2) operative to close off the chamber and shaped so that when the chamber is filled with disinfectant the inside surface of the lid is completely covered by disinfectant, pipework operative to connect supplies of disinfectant to the chamber, a bacterial filter disposed in the pipework and valves (V1 to V8) disposed in the pipework and controlling the flow of disinfectant therethrough.

2. Apparatus as claimed in claim 1, in which means (24, 25, 26) are provided for connecting the pipework to hot and cold water supplies and to a drain.

3. Apparatus as claimed in claim 2, in which the means for connecting comprises quick release connectors (24, 25,26) operative to seal the corresponding pipe on release.

4. Apparatus as claimed in claim 3, in which each quick release connector (24, 25, 26) comprises an automatic closure valve operative to automatically close on release.

5. Apparatus as claimed in any preceding claim, in which the bacterial filter (8) comprises an ultra violet steriliser.

6. Apparatus as claimed in any preceding claim, in which the lid (2) has a re-entrant form.

7. Apparatus as claimed in any preceding claim, in which pump means are provided for circulating fluid through the pipework.

8. Apparatus as claimed in any preceding claim, in which means are provided for sensing the temperature of fluid in the pipework.

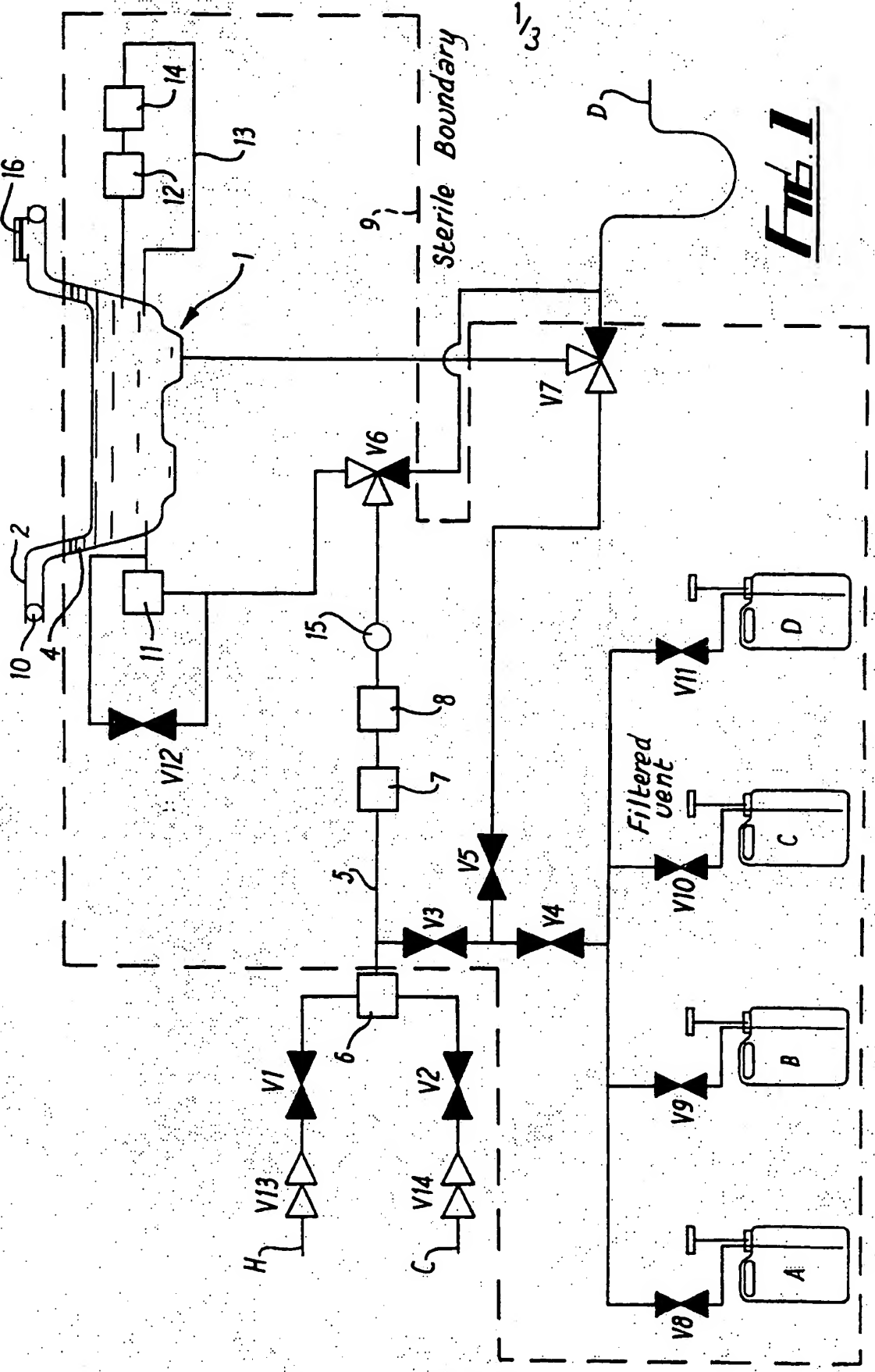
Sterile Boundary
D
V7
V6
V5
V4
V3
V1
V2
V13
V14
V12
V11
V10
V9
V8
Filtered vent
A
B
C
D
H
C
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16

FIG. 1

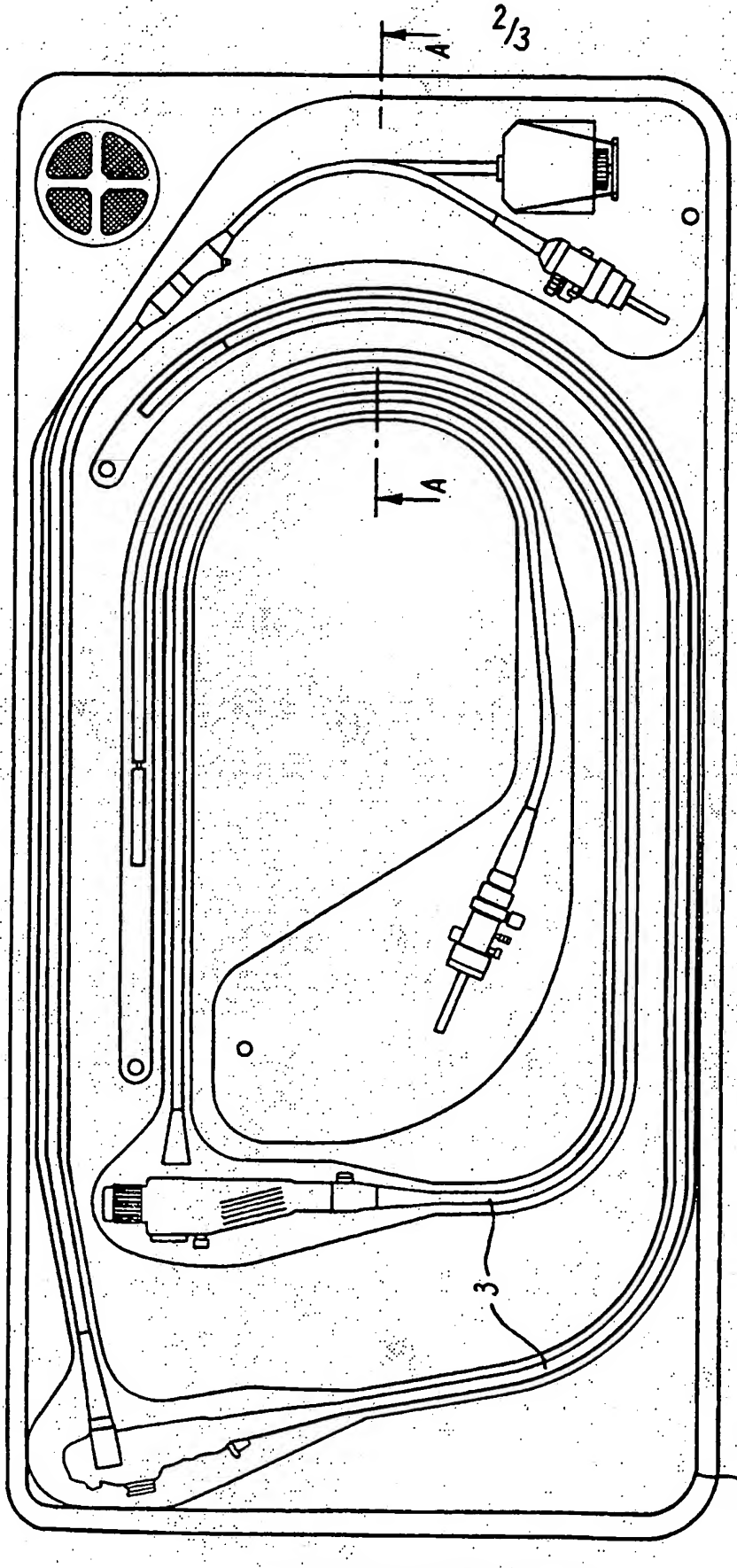

FIG. 2A

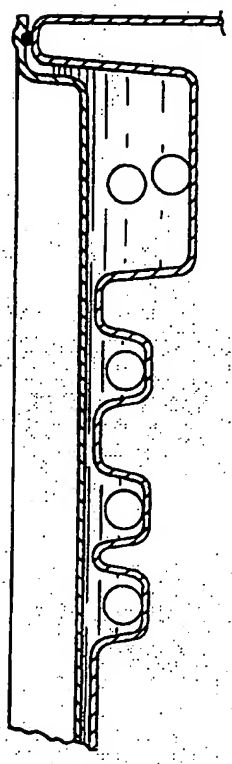

FIG. 2B

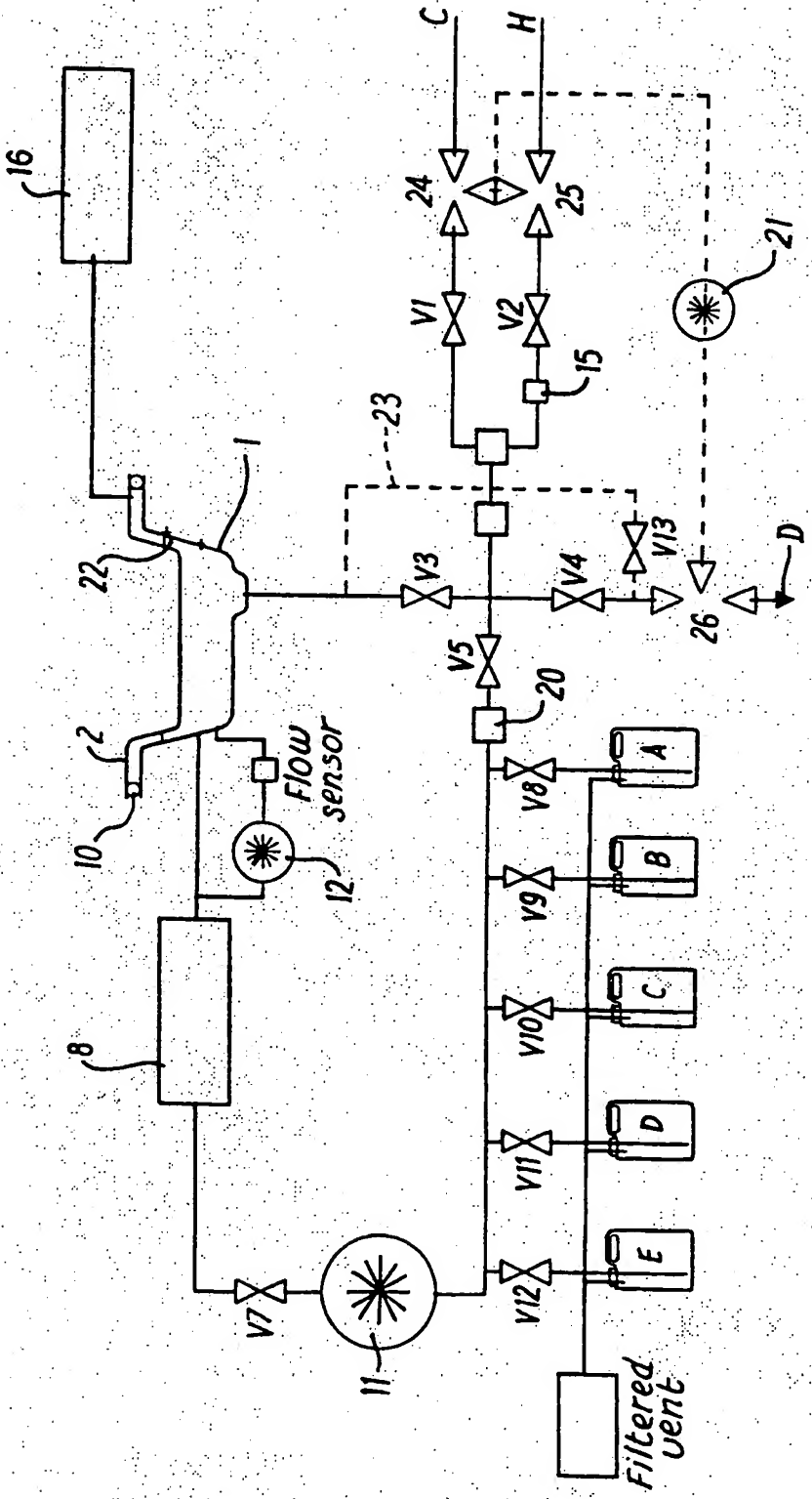
C
H
16
24
25
21
V1
V2
15
23
1
22
V3
V4
V13
D
26
V5
20
2
10
Flow sensor
12
V8
A
V9
B
V10
C
8
V11
D
V12
E
V7
11
Filtered vent

FIG. 3

INTERNATIONAL SEARCH REPORT

Int. onal Application No
PCT/GB 93/01143

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61B1/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61B A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 397 352 (STERIS CORPORATION) 14 November 1990 see column 2, line 15 - column 5, line 34 see figures 1-4	1
A	---	2,4,7
X	EP,A,0 395 296 (STERIS CORPORATION) 31 October 1990 see page 3, line 47 - page 4, line 46 see figures	1
A	---	2,4,5,7
A	US,A,4 862 872 (YABE ET AL.) 5 September 1989 see column 3, line 65 - column 6, line 35 see column 7, line 38 - column 8, line 61 see figures 2,5	1,2,4,5, 7,8

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
12 October 1993	17. 11. 93

Name and mailing address of the ISA	Authorized officer
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	PATENT ABSTRACTS OF JAPAN vol. 016, no. 310 (C-0960)30 July 1990 & JP,A,04 089 045 (AGENGY OF IND SCIENCE & TECHNOL) 23 March 1992 see abstract -----	1,4,7

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 93/01143

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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		JP-B-	4055711	04-09-92
		US-A-	5225160	06-07-93
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		CA-A-	2011124	24-10-90
		JP-A-	2295564	06-12-90
		JP-B-	4055710	04-09-92
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